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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

IN RE: XARELTO (RIVAROXABAN)
PRODUCTS LIABILITY LITIGATION

LOIS CARR,

Plaintiff,

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC,JANSSEN ORTHO LLC,JANSSEN PHARMACEUTICALS,INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS,INC., JOHNSON & JOHNSON COMPANY, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG

Defendants,

COMPLAINT AND JURY DEMAND

Civil Action No.:_____

COMPLAINT

1. Plaintiff, Lois Carr, by and through the undersigned Counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

PARTY PLAINTIFF

2. Plaintiff Lois Carr, ingested Xarelto from approximately September 1, 2017 to September 19, 2017. On or about September 13, 2019, Defendant suffered internal

bleeding, which required surgery and an extended hospitalization, as a direct and proximate result of the unreasonably dangerous characteristics of the prescription drug Xarelto manufactured and sold by Defendants. Plaintiff was also diagnosed at that time with anemia. Plaintiff is a resident of Jefferson County in the state of Alabama.

3. Plaintiff was unaware that the unreasonably dangerous Characteristics of Xarelto caused her internal bleeding.

4. As a direct and proximate result of Defendant's conduct, Decedent experienced physical pain, mental anguish, medical expenses, loss of enjoyment of life, and other economic and non-economic damages.

PARTY DEFENDANTS

5. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business in New Jersey. Accordingly, JANSSEN R&D is a citizen of New Jersey for purposes Of determining diversity under 28 U.S.C. § 1332.

6. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto.

7. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

8. Upon information and belief, and at all relevant times Defendant JANSSEN R&D, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant. The primary purposes of Xarelto are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat Deep Vein Thrombosis ("DVT") and Pulmonary Embolism ("PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

9. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a principal place of business in New Jersey.

10. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and marketing of pharmaceutical products, including Xarelto.

11. Upon information and belief, and at all relevant times, Defendant JANSSEN PHARM was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce

the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

12. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson. The only member of JANSSEN ORTHO LLC is OMJ PR Holdings, which is incorporated in Ireland With a principal place of business in Puerto Rico. Accordingly, JANSSEN ORTHO LLC is a citizen of Delaware, Ireland and Puerto Rico for purposes of determining diversity under 28 U.S.C. § 1332.

13. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products, including Xarelto.

14. Upon information and belief, and at all relevant times, Defendant JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

15. Defendant Johnson & Johnson (hereinafter referred to as "J&J") is a fictitious name adopted by Defendant Johnson & Johnson Company, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

16. As part of its business, J&J, and its "family of companies." Is involved in the research, development, sales, and marketing of pharmaceutical products, including Xarelto.

17. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

18. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto.

19. Upon information and belief, and at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and

for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

20. Upon information and belief, Defendant BAYER PHARMA AG is a pharmaceutical company domiciled in Germany.

21. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG was formerly known as Schering AG and is the same corporate entity as Schering AG.

22. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

23. Upon information and belief, Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011.

24. As part of its business, BAYER PHARMA AG is involved in the research, development, sales, and marketing of pharmaceutical products, including Xarelto.

25. Upon information and belief, and at all relevant times, Defendant BAYER PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

26. Upon information and belief, Defendant BAYER

CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

27. Upon information and belief, BAYER HEALTHCARE PHARMACEUTICALS, INC. is owned by Defendant BAYER CORPORATION.

28. At all relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto.

29. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing Under and by virtue of the laws of the State of Delaware, with its principal place of business located at 100 Bayer Blvd., Whippany, New Jersey 07981-1544.

(a) Upon information and belief, from on or about the early January 1, 2003 until on or about late December, 2014, BAYER HEALTHCARE LLC's sole member was Bayer Corporation, and is wholly owned by Bayer Corporation, which is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

(b) Upon information and belief, from on or about early January, 2015 to on or about June 30, 2015, BAYER HEALTHCARE LLC's sole member was Bayer Medical Care, Inc., and is wholly owned by Bayer Medical Care, Inc., which is a Delaware Corporation, with its principal place of business at 1 Medrad Dr., Indianola, Pennsylvania 15051.

(c) Upon information and belief, from on or about July 1, 2015 to the present, BAYER HEALTHCARE LLC's members are:

- Bayer Medical Care Inc., a Delaware Corporation with its principal place of business in Pennsylvania;
- NippoNex, Inc., a Delaware corporation with its principal place of business in New York;
- Bayer West Coast Corporation, a Delaware Corporation with its principal place of business in California;
- Bayer Essure Inc., a Delaware Corporation with its principal place of Business in California;

- Bayer Consumer Care Holdings, LLC, a limited liability company formed in Delaware with its principal place of business in New Jersey;
- Dr. Scholl's LLC, a limited liability company, formed in Delaware with its principal place of business in California;
- Coppertone LLC, a limited liability company, formed in Delaware with its principal place of business in California;
- Bayer HealthCare U.S. Funding LLC, a limited liability company, formed in Delaware with its principal place of business in Pennsylvania.

30. Accordingly, BAYER HEALTHCARE LLC is a citizen of Delaware, New Jersey, New York, Indiana, Pennsylvania, and California for purposes of determining diversity under 28 U.S.C. § 1332.

31. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise,

promote, market, sell and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

32. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendant BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

33. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

34. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

35. Upon information and belief, Defendant BAYER AG Is the third largest pharmaceutical company in the world.

36. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote,

market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

37. Defendants Janssen Research & Development LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Johnson & Johnson, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG, Bayer Corporation, Bayer Healthcare LLC, Bayer Healthcare AG, and Bayer AG, shall be referred to herein Individually by name or jointly as "Defendants."

38. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

39. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in Interest, and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service,

employment, partnership, and joint venture.

40. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the rug Xarelto.

JURISDICTION AND VENUE

41. Federal subject matter jurisdiction in the constituent action is based upon 28 U.S.C. § 1332, in that in each of the constituent actions there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants

42. Defendants have significant contacts in the vicinage of Plaintiff's residence such that they are subject to the personal jurisdiction of the court in that vicinage.

43. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the vicinage of Plaintiff's residence, as well as in this district. Pursuant to 28 U.S.C. § 139(a), venue is proper in both districts.

44. Pursuant to the Transfer Order of the Judicial

Panel on Multidistrict Litigation, *In re Xarelto (Rivaroxaban) Products Liab. Litig.*, 2014 WL 7004048 (J.P.M.L. June 12, 2014), venue is also proper in this Jurisdiction pursuant to 28 U.S.C. § 1407.

FACTUAL ALLEGATIONS

A. Nature of the Case

45. Plaintiff brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Xarelto, which was designed, manufactured, marketed, sold and distributed by Defendants. Specifically, Plaintiff suffered serious physical pain and suffering, medical, hospital and surgical expenses, as a direct result of Plaintiff's use of Xarelto.

46. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

47. Xarelto was introduced in the United States ("U.S.") on July 1, 2011, and is part of a class of drugs Called New Oral Anticoagulants ("NOACs").

48. This class of NOACs, which also included Pradaxa

and Eliquis, is marketed as the next generation of blood-thinning drugs to replace Warfarin (Coumadin); an established safe treatment for preventing stroke and systemic embolism for the past 60 years.

49. Xarelto is an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15mg, 10mg.

50. Defendants received FDA approval for Xarelto on July 1, 2011 for the prophylaxis of DVT and PE in patients Undergoing hip replacement or knee replacement surgeries (NDA 022406).

51. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" Studies). The findings of the RECORD studies showed that Xarelto was superior (based on the Defendants' definition) to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty accompanied by similar rates of bleeding. However, the studies also showed a greater bleeding incidence with Xarelto leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after

Total Knee Arthroplasty. N. Engl. J. Med. 2008; 358:2776-86; Kakkar, A.K., et al. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after hip arthroplasty: a double-blind, randomized controlled trial. Lancet 2008; 372:31-39; Ericksson, B.I., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. N. Engel. J. Med. 2008; 358:2765-75.).

52. Despite these findings, the RECORD studies were flawed in design and conducted in a negligent manner. In fact, FDA Official Action Indicated ("OAI")-rated inspections in 2009 disclosed rampant violations including, "systemic discarding of medical records," unauthorized unblinding, falsification, and "concerns regarding improprieties in randomization." As a result, the FDA found that the RECORD 4 studies were so flawed that they were deemed unreliable. (Seife, Charles, *Research Misconduct Identified by US Food and Drug Administration*, JAMA Intern. Med (Feb. 9, 2015)).

53. Nevertheless, Defendants received additional FDA approval for Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation on November 4, 2011 (NDA 202439). Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation

in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as "ROCKET AF").

54. The Rocket AF study showed that Xarelto was non-inferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion." (Patel, M.R., et al. Rivaroxaban versus warfarin in Nonvalvular Atrial Fibrillation. N. Engl. J. Med. 2011; 365:883-91.)

55. The ROCKET AF study compared warfarin to Xarelto. Thus, for the study to be well designed and meaningful, the warfarin study group would have to be well managed because warfarin's safety and efficacy are dose dependent. In other words, if the warfarin group was poorly managed, it would be easy for Xarelto to appear non-inferior to warfarin, which, in turn, would provide Defendants a study to "support" Xarelto's use.

56. In fact, in the ROCKET AF study, the warfarin

group was not well managed. The warfarin group in the ROCKET AF study was the worst managed warfarin study group in any previously reported clinical trial involving warfarin.

57. The poor management of the warfarin group in the ROCKET AF study was not lost on the FDA, which noted "the data comparing [Xarelto] to warfarin are not adequate to determine whether [Xarelto] is as effective for its proposed indication in comparison to warfarin when the latter is used skillfully." FDA Advisory Committee Briefing document. P. 10.

58. Public Citizen also noticed the poor control in the warfarin group. Public Citizen wrote the FDA, stating they "strongly oppose FDA approval… The 3 ROCKET AF trial conducted in support of the proposed indication had a suboptimal control arm…" http://www.citizen.org/documents/1974.pdf.

59. Another problem with the ROCKET AF study was Xarelto's once-a-day dosing. The FDA clinical reviewers stated that "the sponsor's rationale for evaluating only once daily dosing during Phase 3 is not strong. Most importantly, there is clinical information from Phase 2 trials… and from clinical pharmacology studies suggesting that twice daily dosing, which would produce lower peak blood levels and higher trough blood levels of [Xarelto],

might have been associated with greater efficacy and/or a better safety profile." FDA advisory Committee Briefing document p. 100.

60. Dr. Steven E, Nissen, more sharply, stated "my concern was that the dose was selected more for a marketing advantage rather than for the scientific data that was available, and was a mistake…" FDA Advisory Meeting Transcript p. 287.

61. Furthermore, the FDA expressed desirability in monitoring Xarelto dosage within their NDA approval memo based on the ROCKET studies. The clinical pharmacology in these studies demonstrated a linear correlation between rivaroxaban (Xarelto)levels and prothrombin time ("PT"); and subsequently a correlation between PT and the risk of bleeding. At this time, Defendants were aware of the correlation between Xarelto dosage and bleeding risks, but had "not chosen to utilize this information." (NDA 202439 Summary Review, p. 9). At all relevant times, Defendants' controlled the contents of their label as demonstrated by their decision to go forward without regard to the FDA's suggestion to utilize this information.

62. The additional indication for treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE was added to the label on November2, 2012.

63. Approval of Xarelto for the treatment of DVT

and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with an increased risk of bleeding events as compared to placebo. (The EINSTEIN Investigators. Oral Rivaroxaban for Symptomatic Venous Thromboembolism. N.Engl.J.Med.2010; 363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study). Expert Rev. Cardiovasc. Ther. 2011; 9(7):841-844). The EINSTEIN-PE study's findings showed that a Xarelto regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEIN-PE Investigators, Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism. N.Engl.J.Med.2012; 366:1287-97.)

64. Defendants use the results of the Rocket AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including

the Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

65. Defendants market Xarelto as an oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism.

66. Defendants market and promote Xarelto as a single daily dose pill that does not require the need to measure a patient's blood plasma levels, touting it more convenient than warfarin and does not limit a patient's diet. The single dose and no blood testing requirements or dietary constraints are marked by Defendants as the "Xarelto Difference."

67. However, Xarelto's clinical studies show that Xarelto is safer and more effective when there is blood monitoring, dose adjustments and twice a day dosing.

68. In its Quarter Watch publication for the first quarter of the 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP"), noted that, even during the approval process, FDA reviewers also questions the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could

be eliminated by twice-a-day dosing."

69. The use of Xarelto without appropriate blood monitoring, dose adjustment and twice-a-day dosing can cause major, life-threatening bleeding events. Physicians using Xarelto have to be able to balance the dose so that the blood is thinned enough to reduce the risk of stroke, but not thinned so much as to increase the risk for a major bleeding event. The Defendants were aware of this risk and the need for blood monitoring but have failed to disclose this vital health information to patients, doctors and the FDA.

70. Importantly, Xarelto's significant risk of severe, and sometimes fatal, internal bleeding has no antidote to reverse its effects, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The original U.S. label, approved when the drug was first marketed, did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdose section.

71. The FDA's adverse event data indicates staggering, serious adverse events that have been associated with Xarelto.

72. In the year leading up to June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including at

least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related death with warfarin.

73. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA, its first full year on the market, Ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

74. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

75. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overlook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

76. Moreover, in the first eight months of 2013, German regulators received 968 Xarelto-related adverse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

77. Despite the clear signal generated by the SAE data, Defendants did not tell consumers, health care professionals and the scientific community about the dangers of Xarelto, nor did Defendants perform further investigation into the safety of Xarelto.

78. Defendants' original, and in some respects, current labeling and prescribing information for Xarelto:

(a) failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto;

(b) failed to provide adequate warnings, about the true safety risks associated with the use of Xarelto;

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient;

(d) failed to disclose the need for dose adjustments;

(e) failed to disclose the need to twice daily dosing;

(f) failed to warn about the need for blood monitoring;

(g) failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto;

(h) failed to adequately disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation

effects of Xarelto;

(i) failed to advise prescribing physicians, such as the Defendant's physicians, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;

(j) failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;

(k) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto;

(l) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially, in those patients with a prior history of gastrointestinal issues and/or upset stomach;

(m) failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Xarelto;

(n) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto;

(o) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient

on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto;

(p) failed to include a "**BOXED WARNING**" about serious bleeding events associated with Xarelto;

(q) failed to include a "**BOXED WARNING**" about serious bleeding events a associated with Xarelto; and

(r) in the "Medication Guide" intended for Distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose the need for blood Monitoring or to patients that there is no drug, agent or means to reverse the Anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

79. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, Including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their

label as detailed in Paragraph 74(a-r).

80. Despite the wealth of scientific evidence, Defendants have ignored the increased risk of the Development of the aforementioned injuries associated with the use of Xarelto, but they have, through their marketing and advertising campaigns, urged consumers to use Xarelto without regular blood monitoring or instead of anticoagulants that present a safer alternative.

B. Over-Promotion of Xarelto

81. Xarelto is the second most prescribed drug for treatment of atrial fibrillation, behind only Coumadin (warfarin), and achieved blockbuster status with sales in the millions of dollars.

82. Defendant spent significant amounts of money in promoting Xarelto, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of fiscal 2013, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

83. Defendants' aggressive and misrepresentative marketing of a "Xarelto Difference" lead to an explosion in Xarelto sales.

84. Defendants' website for Xarelto touts that over forty million people worldwide have been prescribed Xarelto.

and fatal consequences.

85. The Plaintiff was prescribed Xarelto upon having hip replacement surgery and suffered internal bleeding.

86. The Plaintiff was admitted back into the hospital where she had to undergo a blood transfusion.

87. Plaintiff was also diagnosed with anemia as a result of her blood loss due to taking Xarelto.

88. On June 6, 2013, Defendants received an untitled letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

89. Prior to the Plaintiff's prescription of Xarelto, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants claiming that Xarelto was just as effective as Warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more

convenient, without also requiring blood monitoring, dose adjustments, twice daily dosing or adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto and the dangers of them developing anemia.

90. At all times relevant to this action, the Xarelto Medication Guide, prepared and distributed by Defendants and intended for US patients to whom Xarelto has been prescribed, failed to warn about the need for blood monitoring, dose adjustments, and twice a day dosing, and failed to disclose to patients that if serious bleeding occurs, it may be irreversible, permanently disabling, and life-threatening.

91. Prior to applying to the FDA for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of internal bleeding or anemia, which evidence Defendants knew of should have known was a signal that the internal bleeding risk needed further testing and studies prior to its introduction to the market.

92. Even after numerous lawsuits and complaints since Xarelto's introduction to the market, the Defendants still market the drug and claim its effectiveness and safety.

C. THE PLAINTIFF'S USE OF WZRELTO AND RESULTING INJURIES

93. By reason of the foregoing acts and omissions, the Plaintiff was caused to suffer from internal bleeding, anemia, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, expenses for hospitalization and medical treatment, among other damages.

94. Upon information and belief, despite life threatening bleeding findings in a clinical trial and other clinical evidence, the Defendants failed to adequately conduct complete and proper testing of Xarelto prior to filing their New Drug Application for Xarelto.

95. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed and sold Xarelto without adequate warning to Plaintiff's prescribing physicians or Decedent that Xarelto was associated with and/or could cause internal bleeding, anemia, and other severe side effects in patients who used it.

96. Upon information and belief, Defendants concealed and failed to completely disclose their knowledge that Xarelto was associated with or could cause life-threatening bleeding, internal bleeding, anemia and other sever side effects as well as their knowledge that they had failed to fully test or study said risk.

97. Upon information and belief, the Defendants ignored the association between the use of Xarelto and the risk of developing internal bleeding and anemia.

98. Upon information and belief, Defendants failed to warn the Plaintiff and her healthcare providers regarding the need for blood monitoring, dose adjustments and failed to warn of the risk of serious bleeding and anemia associated with Xarelto.

99. Defendants failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for its bleeding risk further rendered the warnings for this medication inadequate.

100. Defendants' fraudulent concealment and misrepresentations were designed to prevent, and did prevent, the public and the medical community at large from discovering the risks and dangers associated with Xarelto and Plaintiff from discovering, and/or with reasonable diligence being able to discover, the causes of their actions.

101. Defendants' fraudulent representations and concealment evidence flagrant, willful, and depraved indifference to health, safety and welfare. Defendant's conduct showed willful misconduct, malice, fraud, wantonness,

oppression, and that entire want of care that raises the presumption of conscious indifference to the consequences of said conduct.

102. By reason of the foregoing acts and omissions, Plaintiff has suffered damages and harm, including, but not limited to, personal injury, medical expenses and other economic harm.

CLAIMS FOR RELIEF

COUNT I

DESIGN DEFECT

103. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-102 as though fully set forth herein.

104. Xarelto is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonable dangerous in its design.

105. At all times material to this action, Xarelto was expected to reach, and did reach, consumers in the State of

Alabama and throughout the United States, including the Plaintiff, without substantial change in the condition in which it is sold.

106. At all times material to this action, Xarelto was designed, developed, manufactured, testes, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to one or more of the following particulars:

a. When placed in the stream of commerce, Xarelto contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to personal injuries;

b. When placed in the stream of commerce, Xarelto was defective in design and formulation, making the use of Xarelto more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market.

c. Xarelto's design defects existed before it left the control of the Defendants;

d. Xarelto was insufficiently tested;

e. Xarelto caused harmful side effects that outweighed any potential utility; and

f. Xarelto was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to the Plaintiff.

107. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants, was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers, and/or, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

108. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and the Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

109. Defendants knew or should have known that at all times herein mentioned, Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

110. At the time of the Plaintiff's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended to act as a prophylaxis DVT for patients undergoing hip or knee replacement surgery.

111. Defendants, with this knowledge, voluntarily designed Xarelto in a dangerous condition for use by the public, and in particular, the Plaintiff.

112. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

113. Defendants created a product unreasonably dangerous for its normal, intended use.

114. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left the hands of the Defendants in a defective condition and was unreasonably dangerous to its intended users, and in particular, the Plaintiff.

115. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

116. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risks of the Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. The safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of the Plaintiff's injuries without substantially impairing the product's utility.

117. The defects in the Defendant's drug Xarelto were a substantial factor in causing the Plaintiff's injuries.

118. By reasons of the foregoing acts and omissions, the Plaintiff's use of Xarelto caused her to suffer from internal bleeding, physical pain and mental anguish.

COUNT II

INADEQUATE WARNING

119. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-118 as though fully set forth herein.

120. Xarelto was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the

Plaintiff, and her health care providers, of the dangerous risks and reactions associated with the subject product, including but not limited to it propensity to cause physical injuries and side effects, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided.

121. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury.

122. Plaintiff was prescribed and used the subject product for its intended purpose.

123. The Defendants, as manufactures and/or distributors of the subject prescription product, are held to the level of experts in the field.

124. The warnings given by the Defendants were not accurate, clear and/or were ambiguous.

125. The Warnings that were given by the Defendants failed to properly warn physicians of the increased risks of permanent physical injuries and side effects.

126. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

127. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

128. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

129. By reason of the foregoing acts and omissions, the Plaintiff's use of Xarelto caused her to suffer from internal bleeding, as well as physical pain and mental anguish.

COUNT III

BREACH OF EXPRESS WARRANTY

130. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-129 as though fully set forth herein.

131. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and/or have acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto to act as a prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

132. Defendants expressly represented to the Plaintiff, other consumers and the medical community that Xarelto was sage and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side-effects and had been adequately tested.

133. Xarelto does not conform to Defendants' express representations because it is not safe, has numerous serious side effects and causes severe and permanent injuries.

134. At the time of making the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

135. At all relevant timed, Xarelto did not perform as safely and an ordinary consumer and the medical community would expect when used as intended or in a reasonably foreseeable manner.

136. Plaintiff relied upon the Defendants' express warranties.

137. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for the use of Xarelto in recommending, prescribing and/or dispensing Xarelto.

138. Defendants breached the aforesaid express warranties, as their drug Xarelto was defective.

139. Defendants expressly represented to the Plaintiff, her physicians, healthcare providers, and the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE and to act as a prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did product were

accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

140. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in fact, produced serious injuries to the uses that were not accurately identified and represented by the Defendants.

141. By reason of the foregoing acts and omissions, Plaintiff's use of Xarelto caused her to suffer from internal bleeding, as well as physical pain and mental anguish.

COUNT IV

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS

142. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-141 as though fully set forth herein.

143. The Defendants impliedly represented and warranted to the users of Xarelto and their physicians, healthcare providers and the FDA that Xarelto was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

144. At all relevant times, Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

145. Defendants were aware that consumers, including the Plaintiff, would use Xarelto in the manner intended.

146. Plaintiff and the medical community reasonable relied upon the judgment and sensibility of the Defendants to sell Xarelto only if it was indeed of merchantable quality and safe and fit for its intended use.

147. Defendants breached the implied warranty to consumers, including the Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

148. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality and was defective.

149. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of the Defendants as to whether Xarelto was of merchantable quality and safe and fit for its intended use.

150. Xarelto was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

151. Defendants breached the aforesaid and implied warranties, as their drug Xarelto was not fit for its intended purposes and uses.

152. By reason of the foregoing acts and omissions, Plaintiff's use of Xarelto caused her to suffer from internal bleeding, anemia, as well as physical pain and mental anguish.

COUNT V

BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE

153. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-152 as though fully set forth herein.

154. Defendants warranted that Xarelto is reasonably fit for its ordinary and intended use.

155. Xarelto is not safe, has numerous and serious side effects and causes internal bleeding.

156. As a direct and proximate cause of the Defendants' actions, Plaintiff was caused to suffer from internal bleeding, anemia, as well as physical pain and mental anguish.

COUNT VI

FRAUD

157. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-156 as though fully set forth herein.

158. Prior to the Plaintiff's use of Xarelto and during the period in which the Plaintiff actually used Xarelto, Defendants fraudulently suppressed material information regarding the safety and efficacy of Xarelto, including information regarding increased adverse events, pre and post marketing deaths, and the high number of severe adverse event reports compared to other anticoagulants and the need for blood monitoring and dose adjustments for the safe and effective use of Xarelto.

159. Defendants fraudulently concealed the safety information about the use of Xarelto. As described above, Xarelto has several well-known serious side-effects that are not seen in other anticoagulants. Plaintiff believes that the

fraudulent misrepresentation described herein was intentional to keep the sales volume strong.

160. The Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff and FDA, and the general public, that Xarelto had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for the prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

161. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto.

162. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Xarelto, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

163. In reliance upon said representations, Plaintiff was induced to and did use Xarelto, thereby sustaining internal bleeding and anemia.

164. Said Defendants knew and were aware, or should have been aware, that Xarelto had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

165. Defendants knew or should have known that Xarelto had a potential to, could and would cause grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

166. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

167. Defendants fraudulently concealed the safety issues associated with Xarelto including the need for blood monitoring and dose adjustments in order to induce physicians to prescribe Xarelto for patients, including the Plaintiff, to purchase and use Xarelto.

168. At the time the Defendants concealed the fact that Xarelto was not safe, Defendants were under a duty to

communicate this information to the Plaintiff, physicians, the FDA, the healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Xarelto.

169. Defendants at all times relevant hereto, withheld information from the FDA and the Plaintiff which they were required to report.

170. Plaintiff's prescribing physicians were not provided with the necessary information by the Defendants, to provide an adequate warning to the Plaintiff.

171. Xarelto was improperly marketed to the Plaintiff and her prescribing physicians as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about Xarelto's risks.

172. As a direct and proximate result of the Defendants' malicious and intentional concealment of material life-altering information from Plaintiff and her prescribing physicians, Defendants contributed to Plaintiff's injuries.

173. Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of Xarelto.

174. Defendants widely advertised and promoted Xarelto as a safe and effective medication and/or as a safe and effective means of reducing risks and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

175. Defendants advertisements regarding Xarelto falsely and misleadingly states that blood monitoring and dose adjustments were not necessary for safe and effective use of the drug, misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as the Plaintiff, to purchase such product.

176. Defendants had a duty to disclose material information about serious side effects to consumers such as the Plaintiff and a duty to disclose all facts about the risks associated with the use of the medication, including the risks described in this Complaint.

177. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such and the Plaintiff, to purchase the Defendants' product.

178. Had the Plaintiff been aware of the hazards associated with Xarelto, Plaintiff would have employed appropriate blood monitoring, consumed a different anticoagulant

with a better safety profile, or not have consumed the product that led proximately to the Plaintiff's injuries.

COUNT VII

VIOLATION OF CONSUMER PROTECTION LAWS/CONSUMER FRAUD

179. The Plaintiff re-alleges and incorporates by reference herein all the allegations contained in paragraphs 1-178 as though fully set forth herein.

180. Plaintiff used Xarelto and suffered ascertainable losses as a result of Defendants' action in violation of the consumer protection laws.

181. Defendants use unfair methods of competition or deceptive acts or practices that were proscribed by law, including:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

182. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Xarelto.

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action awarding all amounts which are reasonable in the premise, including:

a. Compensatory damages
b. Economic Damages
c. Punitive and/or exemplary damages
d. Prejudgment interest
e. Post judgment interest
f. Plaintiff's reasonable attorney fees
g. Plaintiff's costs of these proceedings, and
h. Such other and further relief as this Honorable Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by stuck jury as to all issues.

Respectfully submitted,

By:/s/ Monica Austin-Hatcher
Monica Austin-Hatcher

/s/ LaShunta White-Boler
LaShunta White Boler

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